Science *in* Donation and Transplant

February 1, 2022

The Honorable Chiquita Brooks-LaSure Administrator
Centers for Medicare & Medicaid Services US Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244
Ref: CMS-3409-NC

Re: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

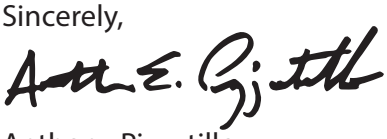
Dear Administrator Brooks-LaSure:

Science in Donation and Transplant (SID&T) is a non-profit organization devoted to the support and education of members and stakeholders in the donation and transplant communities and founded on the belief that donors and transplant recipients alike deserve a well-aligned, peer reviewed science-based system.

SID&T advocates in concert with leading medical practitioners for enhanced coordination and alignment among organ procurement organizations (OPOs) and transplant centers. Our goal is to ensure that the metrics and measures used to credential, license, designate and certify donation and transplant organizations are grounded in science and protected from political whim and private financial influence.

On behalf of Science in Donation and Transplant, and in support of the over 106,000 patients waiting for a life-saving transplant, we appreciate the opportunity to respond to the Request for Information (CMS-3409-NC).

Sincerely,



Anthony Pizzutillo
Chair
Science in Donation and Transplant (SID&T)

We, and many peers in the field, know from fact-based experience that improving accessibility and outcome for patients and the overall efficiency and effectiveness of the donation and transplant system requires certain CMS encouraged goals:

- Encouraging the proper alignment and cooperation among Organ Procurement Organizations, Transplant Centers, Hospitals and community partners.
- Recognizing that the certification and decertification metrics for OPOs need revision. Transplant centers need to be part of the equation as they, not OPOs, control the outcome. Decertifying OPOs based on transplant rates fails both public policy and basic logic tests.
- The many questions raised by the Rule's failure to address all of the critical criteria and timeframe questions of potential de-certification of up to two-thirds of existing OPOs, and the potential negative impact this poses to the most at-risk populations, demand the establishment of a National Task Force of science-based experts and community stakeholders to study the issues and make recommendations.
- The truly sensitive nature of organ donation and procurement begs for CMS to protect, nurture and improve the community-based non-profit system.

SID&T wholeheartedly supports CMS' effort to obtain factual input from a broad spectrum of organizations and individuals with hands-on experience in donation and transplant processes. It is through action like this that the United States has developed the most effective system of organ donation and transplantation in the world, and one which is consistent with our nation's highest ethical values of voluntarism and altruism.

In response to the agency's note of a 6% rise in donation since 2019, we highlight the fact that donation and transplant rates have consistently risen since 2015, and we trust that CMS' continuing focus will extend this trend.

We further applaud the agency's effort to gather data on potential biases in donation, and particularly in transplant, and hope that this RFI, as well as other collaborative efforts, will promote best practices, reward those who best serve diverse populations, and support improved practices for stakeholders in areas where services for under-resourced and minority populations are lacking.

We are concerned that most of the entities headed for de-certification under the latest data publication from CMS are OPOs whose service area demographics are disproportionately minority. First, the research has not been done to determine if these OPOs are being fairly evaluated given the impact on their certification on factors they cannot control such as transplant rates.

Second, given the multi-year time frame for the successful integration of "friendly" OPO mergers, frightening questions are raised about how those populations will be served. OPOs may have higher net numbers, but lower numbers of minorities donating and being transplanted. We feel this lack of measurement might hide,

at best, useful truths about performance, and, at worst, patterns of bias in otherwise high performing OPOs. There is also a grave concern that by pitting OPOs against each other, which the Rule seems to encourage, collaboration between and among these lifesaving organizations will actually become a liability.

Finally, given CMS' one year timeframe for improvement, what high performing OPO will take over a lower performing area given the extraordinary cost and logistical issues which experience shows take years to work through? The fact-based experience of the time needed for "friendly" OPO mergers raises a stark question unaddressed by the Rule. There is an extraordinary cost associated with decertification. Who will be responsible for the fiscal issues related to physical facilities, buildings, labor, affiliates, and contractors? Is the door being opened to an avalanche of potential lawsuits given the uncertainty around these issues?

SID&T does not support that portion of CMS's well-meaning but misguided effort to improve donation by mandating the closure of donation organizations thereby putting more focus on quantity than quality. The current CMS metrics which evaluate the OPOs equally on donation and transplant fail both logic and public policy tests. This is not a race to see how many chips can be placed in how many computers. Transplant centers need to be aligned with OPOs to share in the evaluation of transplant rates. They are the controlling force. The sensitive non-profit role of organ procurement needs to be recognized and nurtured.

We urge CMS to focus instead on researching and testing best practices, supporting these, and measuring performance based on adherence by ALL participants in the donation and transplant system to aligned action plans. We support science over the likely chaos caused by widespread decertification and the planned phased mass closures of community-based donation organizations.

This harms the carefully designed transplant ecosystem of the National Organ Transplant Act, and does a disservice to the nation's donor families and hopeful recipients of those donor organs. We urge more learning, talking, studying, alignment and implementation of measurable adherence to identified best practices, not closure of entities based on snapshots of uninterpreted, raw, outdated data.

Our comments regarding specific requests for information for the issues of primary concern to us are included below:

1. The Role of Competition in the Improvement of the Transplant Ecosystem:
SID&T has numerous concerns about the competitive model imposed by the Rule, and its ability to improve the transplant ecosystem. We think that the system of terminating the ability of existing nonprofits to facilitate organ donation in their communities, in favor of unknown, and possibly unwilling, foreign entities assuming the same role in expanded territories is not a design for a successful system. We also fail to see how "competition" between non-profits for altruistic gifts of human body parts fits within an ethical structure dependent on

human generosity. We have concerns that the numbers-based competitive model is not designed to foster the trust upon which the entire system is based.

A systems-based analysis of the so-called "incentivizing" of performance by threat of closure reveals that the actual goal of the current regulatory scheme is not improvement, but rather consolidation. This is demonstrated by the fact that the Rule provides for decertification of a set percentage of entities each cycle, without regard for the proven actual ability of any other entity to do better under the same geographic, demographic, cultural and health care access conditions. The proposed business model style is not one conducive to the altruistic values of donation and transplantation that is dependent on public trust.

As SID&T provides useful responses to the questions posed in this RFI, it cannot avoid the conclusion that closure and consolidation is not only the goal of the Rule, but that insufficient thought has gone into the impact such closures will bring about. One question is both particularly revealing, and particularly chilling in this regard:

Although we believe our new assessment approach will incentivize OPO performance, resulting in clustering of rates close to the highest performers, eventually the margin between the top 25 percent and the median will begin to narrow. Once OPO performance on the outcome measures reaches this level, CMS will need to consider other factors that differentiate highly functioning OPOs from those that are less highly functioning.

In other words, CMS assumes that its closure of up to a third of all OPOs in a cycle will result in higher numbers of organs procured and transplanted by the newly acquiring OPOs, an assumption which ignores universally accepted models of the impact of mergers and takeovers.[1] But, even when the assumed improvements have occurred, the new system requires a certain number of OPOs to be decertified, regardless of their rate of improvement, their adherence to standards, their ability to serve the community they find themselves in. Is this a peer-reviewed science-based calculation or an arbitrary or politically charged percentage one? This question begs to be reviewed by an expert National Task Force.

SID&T's response is that CMS is not following the proper metrics:

The right question is not how do we close OPOs, but rather, what evidence-based practices can we bring to challenged service areas to support improved donation rates? These might include quality audits, peer-advisement, governance review, management agreements, staff training, ecosystem collaboratives, and other proven methods for quality improvement. Decertification, or the threat of decertification has never been demonstrated to improve healthcare quality. Nor has bigger been proven to be better in delivery, especially when that service is based on the willing participation of human beings, donors, and their families.

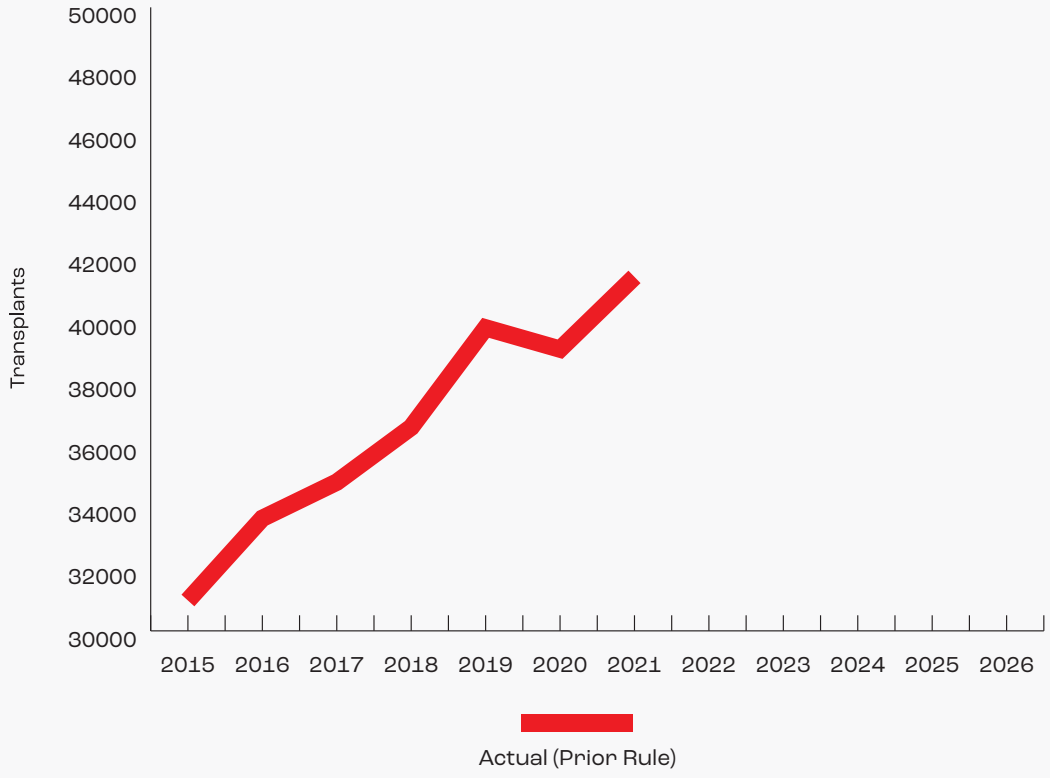
The transplant ecosystem has a proven model for achieving improvement. That model is found in the 2003 Organ Donation Breakthrough Collaborative ("the Collaborative"). The impetus for these successes was the alignment of transplant community goals with all of the four Collaborative channels (transplant centers, donor hospitals, organ procurement organizations ("OPO"), and community partners) all coordinated and measured against the same metrics. Each Collaborative participant had a role to play in increasing performance measured by one or more of the three primary metrics and all were held accountable for the donor service area's success or failure. The ultimate goal was system improvement and not punitive action for underperformers. By 2006, the Collaborative had generated incredible results with record-breaking increases in organ donation and the number of transplants performed.

As an example, setting a goal of increasing the average number of organs recovered from a donor to 3.75 each required OPOs to focus on best practices for achieving donor consent and improved recovery techniques to ensure every viable organ was recovered 100% of the time. It required transplant centers to accept organs to ensure all organs recovered were seriously considered for transplant and to reduce transplant center organ discard rates. It required donor hospitals to partner with OPOs on effective authorization practices and to enable early medical intervention with registered donors which increased graft survival and the number of organs viable for recovery and transplant. It encouraged OPOs and donor hospitals to take advantage of increases in legal donor authorization driven by Collaborative community partners via promotion of state donor registries and to act on this legal consent 100% of the time. It also encouraged improved donor management processes by OPOs in collaboration with donor hospitals. This single performance metric engaged all four Collaborative channels and created alignment of community goals with each channel having a role in, and responsibility for, improvement.

The historic success of the Collaborative is undeniable, and HHS should be commended for leading this effort. Current proposed metrics for OPO performance, however, focus on a single channel (OPOs) and do not create alignment of community goals. It seems wrong, therefore, to continue holding OPOs solely accountable for the entire organ procurement and transplantation process. This is short-sighted, not based on any proven best practice for system improvement and certainly is not creating community alignment.

The drive for improvement in donation, so encouraged by the Breakthrough Collaborative, has not only continued, but increased in the last decade. In the last seven years, as demonstrated in the graph below, the rate of increase in deceased donations has outperformed the target rate of the Rule. These improvements did not come about through threat of disruption and closure; they came about through trial and error, data collection, data analysis and quality improvement. It is hard to believe that consolidation for its own sake will not threaten the continuous arc of improvement already achieved.

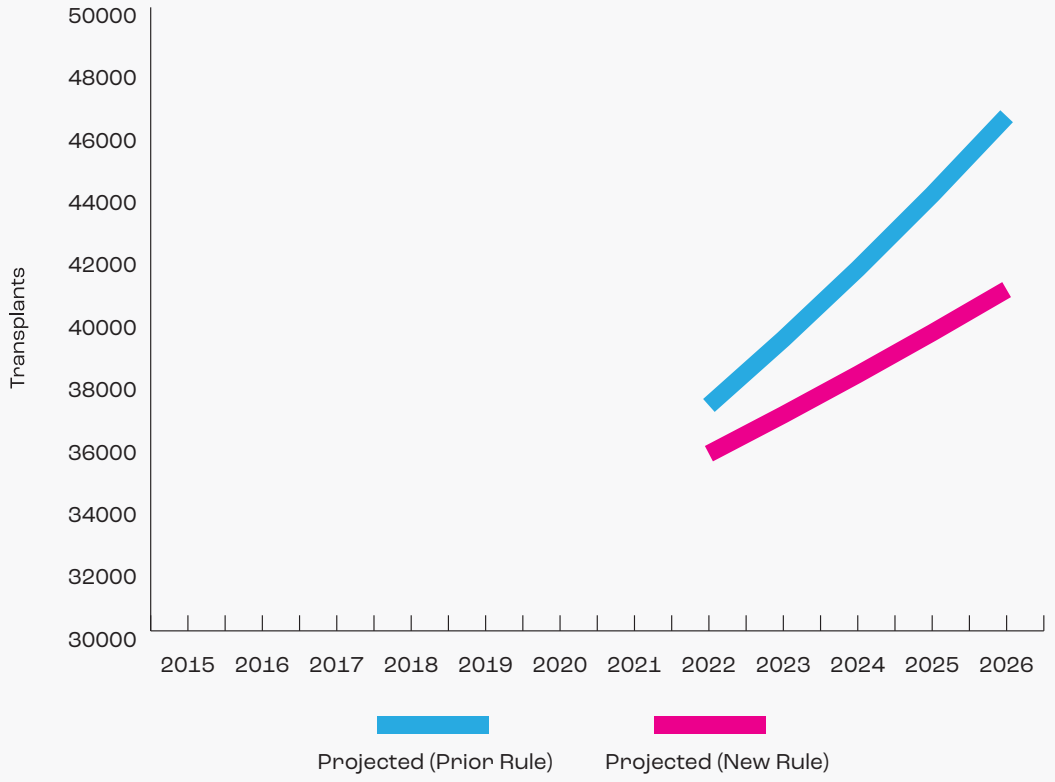
Actual (Prior Rule)



Actual data from OPTN National Data Reports.

OPOs, building on the successful cooperation of the Breakthrough Collaborative, provided 41,354 transplanted organs in 2021 greatly exceeding CMS' projected 35,442

Projected Prior v. Existing Rule



Prior rule projections calculated by Donate Life America. CMS rule projections based on CMS new rule goals.

CMS' Rule sets back increased transplant projections by five years versus the previous rule. Blue line represents independent projection under the previous rule and the magenta line the lagging consequences of the current Rule.

2. Equity:
SID&T wholeheartedly supports the commitment to the advancement of racial, gender, sexual orientation and disability status-based equity in access to transplant. Deep concern surrounding the Rule's position on diversity and equity is one of the core values of this non-profit. [2] It is heartening that this RFI seeks input concerning how best to ensure that the well-documented disparity in transplant is addressed.

Let's look again at the roles in improving racial disparity:

If donor hospitals are following current regulations by referring every potential donor to OPOs, an action which is regularly reviewed and reported by that OPO, there is no opportunity for racial bias in procuring organs. OPOs, correspondingly, must review every referral received. Their response is compiled and reported whether it be a ruled-out organ or one to pursue for potential donation. Incentives for OPOs to recover all donors are aligned; there is no 'reward' for failing to follow up on a donor of any particular background or ethnicity, quite the contrary.

The policies which support donation and recovery of organs should support all donors equally, i.e., counting work performed by the OPO even when unforeseen clinical determinants render a given donor a "zero organ donor" or provide organs suitable only for research.

In a true case of a "rising tide raises all boats", acknowledging the work of OPOs, even when the reward of a transplantable organ may be less likely, serves all patients on the list.

There is no direct correlation between the number of underserved or minority organ donors and underserved and minority transplant recipients, other than the fact that every organ donor shortens the list of recipients. There is, in short, no guarantee that recovery of more organs from minority donors will somehow narrow the discriminatory gap that exists in transplant. The gap that exists in transplant exists due to the age-old, unacceptable social determinants of health care access, including education, socioeconomic disadvantage, heightened rates of kidney disease and need, and, it seems, some clinical policy issues, such as the use of race in eGFR equations.

SID&T questions how OPOs can impact racial disparities in transplant[3], when again, all OPOs can do is raise the tide to lift all the boats. Neither donor hospitals nor OPOs list patients for transplant. The answer to the question on racial disparity in transplantation rests with transplant physicians, centers and policies.

The information sought on how OPOs can better raise donation rates among diverse communities, is, however, very well-taken. Because leaving a life-saving legacy through organ donation is a civil right, and because the ability to save lives through altruistic donation should be equally accessible to all, OPOs must not waver in their efforts to reach all the communities in their service area with culturally sensitive communication, donor registry messages, and donor education.

SID&T supports the gathering of current data which identifies best practices with regard to each cultural community, and notes that the form best practices will take are likely to be as diverse as the communities OPOs serve. What works with Orthodox Jews in New York will be different than what works with the Hmong population in Minneapolis, or the native American population in New Mexico, or the diverse communities of Philadelphia and Camden and Los Angeles, where diverse 'minority' group members make up the 'majority' of the population.

Existing statistics on donation from diverse communities show marked differences in the success rate of OPOs in serving minority communities, and these successes must be measured, quantified and disseminated. As consensus best practices emerge, their implementation can become a benchmark, or even a regulatory requirement.[4]

Failing to identify quantifiable best practices, we contend, risks punishing those service areas where an OPO may serve its diverse group at a statistically optimal rate, yet still faces decertification. We take this risk very seriously.

3. Comprehensive Alignment:
SID&T appreciates the recognition, reflected in the fact and focus of this RFI, that treatment, donation, and transplant are part of a continuum of care and public health. The term "transplant ecosystem" as utilized in the RFI encapsulates this reality perfectly.

While the processes must all work together, we must appreciate that each player has a primary role to play.

a. The role of OPOs in Transplant:
With regard to the assigned role of each player, SID&T does not see the public policy or health care logic, reflected by both the Rule and this RFI, that OPOs play a measurable role in whether the organs they recover are transplanted. A cardinal tenet of accountability is that one can only be accountable for things one influences or controls. The surgical recovery of organs, the acceptance of organs for a particular patient, even the allocation of organs is not within the lawful control of OPOs and should not be included in Conditions of Participation (COPs). Thus, the response we provide to the question:

"Transplant Recipient Patient Rights (We are interested in understanding how the COPs…could be revised to ensure that …OPOs…are providing appropriate education and information to patients and their families on organ transplantation"

is that OPOs do not provide education to organ recipients about transplantation. As the entity's name, and NOTA indicate, OPOs do donation and procurement, but they are not the primary medical or educational resource for transplant patients, the prospective recipients of the organs OPOs help obtain.

Many OPOs benefit from the volunteer services of grateful organ recipients, but do not get involved in decision making when it comes to organ allocation. It is one of the truly unique elements of the donation system, as created by its statutory founders under NOTA, that OPOs are ethically bound to serve donors and donor families with singular focus, to the ultimate benefit of transplant patients, many of whom an OPO will never see. This separation is essential to the OPO role of serving ALL recipients, everywhere in the country. OPO services are focused on obtaining recovered organs from the general public, and continuing to engage with and honor donor families, in order to serve potential recipients.

Likewise, while SID&T is encouraged by the newfound recognition that equity in donation should be measured, for the good of all, we note again, in response to the question:

"Are there revisions that can be made to the …OPO CfC's to reduce disparities in …organ ***transplantation****"* *(emphasis added),*

The answer is "no", because OPOs do not have a say in who gets transplanted, only in who gives organs to the list.

This fundamental misunderstanding of the role played by OPOs in the transplant ecosystem was initially promulgated in the Rule[5], but the RFI's inquiries into additional areas for OPO Assessment double-down on the erroneous assumption that OPOs control transplant, or make transplant decisions: ("Should CMS consider additional metrics, such as those that measure…an OPOs success in reducing disparities in …. transplantation…?) This misapprehension of the respective roles of the players at best ignores reality and at worst puts lives at risk in the chaos of improperly judged de-certification.

b. The Role of Transplant Centers and Donor Hospitals:

The Rule focuses entirely on OPOs and ignores the role of transplant centers in the donation and transplant process. The Rule judges OPOs on two metrics. One is the donation rate, and the other is the transplant rate. Judging OPOs on the donation rate makes perfect sense; it's what OPOs do. Scoring OPOs on the transplant rate is a significant flaw in the Rule. Transplant centers are solely responsible for the transplant rate and the discard rate. In this Rule, OPOs are held accountable for actions in which they have no role. Transplant centers decide on organ utilization, not OPOs.

These are subjective decisions made by transplant doctors at transplant centers. Unfortunately, there is no transparency for transplant centers' decisions, unlike OPO operations. Patients rarely have knowledge about how many organs have been rejected on their behalf. As referenced by Dr. Marty Sellers at the NASEM Health and Medicine Virtual Listening Session on July 16, 2021, an average of 16 kidneys are rejected before the center decides to use an organ for transplant.

Transplant centers need to be accountable for patients on their waiting list. It's a known fact that the longer a patient stays on dialysis, the poorer the outcome once they are transplanted. It begs credulity that a patient is better served by staying on dialysis, sometimes for years, while ultimately waiting for the 16th kidney when the eighth offered has the same KDPI score. Again, these are subjective decisions made by doctors with little or no transparency.

Transplant centers have no incentive to change their practice regarding the discard rate. There is no reason to believe that adding more organs to the current system will result in better outcomes. Transplant center metrics must be part of any reforms to the transplant ecosystem.

There is no better example in medicine where a team effort is crucial to patient survival. OPO and transplant center metrics must be aligned to save more lives. The RFI begins to address these issues. The need for system-wide reform has been overdue for many years. Changing OPO metrics alone will not solve the problems facing organ donation and transplant.

Donor hospitals from where all organ donors arise, and their performance, like that of transplant centers and OPOs, are another significant participant in the transplant ecosystem, and are subject to The Medicare Conditions of Participation for Hospitals. COPs detail requirements for Hospital and OPO collaboration [6] and JCAHO standards also include quality measures for a donor hospital's performance of its obligations.[7]

Yet, it is likely that donor hospitals account for an appreciable number of losses of recoverable organs, and absent specific enforceable standards, the only recourse against poor cooperation is draconian adverse event reporting by the OPO.[8] The system depends on collaboration, not calling the other out and hence OPOs do not have an incentive to report offenders, and have much to lose by making an adversarial report. Donor hospitals require specific support and guidance from CMS about the importance of their role, and it should not be up to an OPO to enforce CMS' rules through reporting. Among the donor hospital issues that continue to adversely impact organ donation:

- Encouraging the proper alignment and cooperation among Organ Procurement Organizations, Transplant Centers, Hospitals and community partners.
- Recognizing that the certification and decertification metrics for OPOs need revision. Transplant centers need to be part of the equation as they, not OPOs, control the outcome. Decertifying OPOs based on transplant rates fails both public policy and basic logic tests.
- The many questions raised by the Rule's failure to address all of the critical criteria and timeframe questions of potential de-certification of up to two-thirds of existing OPOs, and the potential negative impact this poses to the most at-risk populations, demand the establishment of a National Task Force of science-based experts and community stakeholders to study the issues and make recommendations.

- The truly sensitive nature of organ donation and procurement begs for CMS to protect, nurture and improve the community-based non-profit system.

There are ways to quantify the prevalence of this practice, which has been, to date, largely supported only by dated or anecdotal evidence. The right to donate is guaranteed by state and federal law. It is a right to leave a legacy. In these extreme circumstances, donor hospitals should be held accountable, and it is not only within the purview of CMS to address it, but also their responsibility.

4. Research:

a. Donation and Transplant System Science:

SID&T strongly supports academic and transplant ecosystem-based research into many of the areas inquired about in this RFI. Much new research is clearly needed. It is one thing to inquire as to first- hand knowledge of efforts to combat bias; it is quite another to evaluate and quantify the problem and assess the merits of a given best practice. We hope this RFI is the genesis of a burgeoning interest in scientific study of what works and doesn't in donation and transplant.In the past, HRSA and the Division of Transplantation have been major sources of funding and support for projects testing various theories and projects surrounding attitudes surrounding donation, targeted efforts to address failure to register, failure to authorize, and other issues of concern in donation and transplantation.

It is safe to say that many of the best practices utilized today arose from projects first piloted with federal grants. These grants have been gradually diminished over time, leading to a dearth of current data, and the imposition of politicized attack rhetoric in place of positive solutions. This distracting discourse is creating a second wave of "crisis in donation" by directly attacking public trust, the foundation without which altruistic giving CANNOT occur.

We hope that this RFI directs CMS' attention to the numerous solutions that are being tried and tested in the transplant ecosystem, and that the best of these ideas receives rigorous and peer-reviewed analysis and testing, not by private think tanks, but respected academic and medical institutions. In short, rather than focus on just the opinions of the community as to what works, we believe a role for the regulator ecosystem is to invest in public health research into vital issues, with the goal of supporting what works.

b. OPO provision of research organs and tissues:

As a corollary response, SID&T is mindful that the availability of organs and tissues for scientific and medical research is a humanitarian goal that organ procurement organizations are well-positioned to facilitate. Moreover, for a family who donates, but later learns that an organ was clinically non-transplantable, the thought that the organ was put to other good use can be very comforting. The nature of biospecimen research is such that a responsible OPO is required to put time and effort into the responsible sharing of all organs, not just

pancreata, for research and given the need for research and the effort entailed, it stands to reason that it is equitable to measure an OPOs success in this effort, as in all its altruistic efforts.

Given that all of an OPOs agreements are subject to audit and review by the Secretary, we fail to understand the RFI's reference to "self-reporting" of research participation. For decades, research organs and tissues have been provided by OPOs to public and private research facilities, academic research centers and others, with donor consent and a fully auditable chain of custody. Many of the most groundbreaking research successes of the past decades, including the mapping of the human genome and strides in diabetes treatment and transplantation science, have been accomplished through the provision of donated human organs facilitated by OPOs. IRB approvals routinely inquire as to the source of biospecimens used for research. If CMS needs to know when an organ has been shared for research, the data is available to them.

SID&T is grateful for the opportunity to submit these responses to CMS, and applaud the care and focus of the Secretary on these issues.

[1] For a surprisingly pertinent discussion of the risks, benefits and expectations for merged and acquired entities, see 4 Biggest Merger and Acquisition Disasters, accessed at 1/25/2022 at https://www.investopedia.com/articles/financial-theory/08/merger-acquisition-disasters.asp

[2] The Final Rule states :"… we are not aware of a biological reason why race, as an independent factor, would affect the decision to be an organ donor or the number of organs transplanted." We believe this statement

wrongly discounts existing data that shows differences, not just of 'biology' but of culture, poverty, access and other systemic issues, and incorrectly concludes that those differences are only caused by "OPO biases and shortcomings."

[3] "Should CMS consider additional metrics, such as …an OPOs success in reducing disparities in… transplantation?"

[4] SID&T notes that the RFI relies upon articles containing data that is fifteen years old, where its own SRTR data, or even the articles by the same author, Laura Siminoff, based on data more recently compiled, might be more relevant and instructive on actual current OPO performance among diverse groups. See e.g. Siminoff LA, A Comparison of the Content and Qualityof Organ Donation Discussions with African American Families Who Authorize and Refuse Donation Journal of Racial and Ethnic Health Disparities ISSN 2197-3792

DOI 10.1007/s40615-020-00806-7, which at least compiles data that is less than ten years old.

[5] https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf

[6] 42 C. F. R. § 482.45

[7] See, generally https://www.jointcommission.org/

[8] 42 CFR § 486.302